

Exhibit D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC. PELVIC Master File No.
5 REPAIR SYSTEM PRODUCTS LIABILITY 2:12-MD-02327
6 LITIGATION MDL No. 2327
7 THIS DOCUMENT RELATES TO JOSEPH R. GOODWIN
8 PLAINTIFFS: US DISTRICT JUDGE

9
10 Mary Cone
11 Case No. 2:12-cv-00261
12 Dina Destefano-Raston
13 Case No. 2:12-cv-01299
14
15 Shirley Freeman
16 Case No. 2:12-cv-00490
17 Carrie Smith
18 Case No. 2:12-cv-00258

19 (Continued on next page)

20 - - -
21 APRIL 4, 2016
22 - - -

23 Deposition of BARRY SCHLAFSTEIN, MD, held at
24 Hilton Garden Inn Savannah, Scarborough Conference
 Room, 321 West Bay Street, Savannah, Georgia 31404,
 commencing at 9:03 a.m., on the above date, before
 Joan L. Pitt, Registered Merit Reporter, Certified
 Realtime Reporter, and Florida Professional
 Reporter.

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1 (Continued from previous page)

2 Donna Zoltowski

Case No. 2:12-cv-00811

3

Roberta Warmack

4 Case No. 2:12-cv-01150

5 Fran Collins

Case No. 2:12-cv-00931

6

Noemi Padilla

7 Case No. 2:12-cv- 00567

8 Jennifer Sikes

Case No. 2:12-cv-00501

9

Isabel Swint

10 Case No. 2:12-cv-00786

11 Krystal Teasley

Case No. 2:12-cv-00500

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1 to be fair.

2 Q. So at some point during the first quarter of
3 2016, you believed there to be over 950 TVT products
4 that you had placed in women suffering from SUI;
5 correct?

6 A. Correct.

7 Q. Same question with regard to Prolift and
8 Prolift+M, which, as you established earlier, it's no
9 longer on the market, so it would be more of a static
10 number?

11 A. Well, I don't have the number of Prolift or
12 Prolift+M. I have the number of transvaginal mesh
13 procedures, which would include Prolift and Prolift+M,
14 and it would include other types of meshes.

15 So that would be -- that number, which would
16 include all the transvaginal meshes, would be greater
17 than 630 transvaginal procedures. Transvaginal mesh
18 procedures.

19 Q. Greater than, did you say, 600?

20 A. 6-3-0.

21 Q. 6-3-0.

22 Do you have any way to quantify, of those 630
23 procedures, approximately how many would have been
24 Ethicon products versus other manufacturers?

1 A. No, I'd have to go back. I'd have to do a
2 little more detailed analysis, which would be the
3 date -- you know, looking at the dates of the procedures
4 and before and after.

5 MR. OTTAWAY: Doctor, he didn't ask you how
6 you'd do it. He asked you if you did do it.

7 THE WITNESS: No.

8 MR. OTTAWAY: So just try to listen to the
9 question and answer it. He's entitled to a direct
10 answer to a direct question.

11 A. Can you repeat the question, please?

12 MR. SCHNIEDERS: Can you read it back? I lost
13 it.

14 (The question was read by the reporter.)

15 THE WITNESS: Not at the moment.

16 BY MR. SCHNIEDERS:

17 Q. And I believe, based upon your answer earlier,
18 the only way to do that would be a chart search; is that
19 correct?

20 A. That is correct.

21 Q. Because the billing for that procedure is more
22 of a general billing code that would encompass all
23 products; correct?

24 A. It would encompass all transvaginal mesh

1 yourself that you cited it in your report, for the most
2 part?

3 A. Yes, for the most part, yes.

4 Q. Okay. So there may be a couple odds and ends
5 on here that you also requested that you didn't end up
6 putting into your report, but for the most part, if it's
7 not in your report, it's likely something that the
8 defendant provided you?

9 A. I think that's fair.

10 Q. Did you read every document that is on your
11 reliance list?

12 A. I did not read every single document that's on
13 this reliance list, no.

14 Q. For instance, if you go to, they're not
15 numbered, but the third or fourth from last page, do you
16 see at the bottom there are several documents with a
17 convention code that says "ETH.MESH" and then "."
18 numbers?

19 Do you see that?

20 A. Yes.

21 Q. Is it fair to say that you didn't request those
22 documents?

23 A. That is fair to say.

24 Q. Is it fair to say that you didn't review those

1 documents?

2 A. That is fair to say.

3 Q. Similarly, if there are some internal documents
4 that are listed on this reliance list, based upon your
5 testimony previously, it's fair to say that those
6 weren't things that you read and considered in your
7 expert report; right?

8 A. And just to be clear, by "internal," you're
9 referring to?

10 Q. Documents, e-mails, things that were only
11 between Ethicon employees.

12 A. The answer then would be correct.

13 Q. You did not review those?

14 A. Correct.

15 Q. And you did not consider them in forming your
16 opinions; correct?

17 A. Correct.

18 Q. You can set that to the side, Doctor.

19 As we look back at your invoice here, I believe
20 it's Exhibit 14, there are notations like "write Prolift
21 general," "chart review," "telephone conference," but I
22 don't see anything that says "review of literature."

23 A. Yeah.

24 Q. Is there anything in there that would fall

1 Q. Doctor, if you would go to page 4 of Exhibit 2.
2 There is -- about halfway down the page, you've listed
3 several professional societies by name stating that they
4 have offered up statements in support of mesh.

5 Do you see that?

6 A. I do.

7 Q. And are there also societies that have spoken
8 out against mesh?

9 A. Well, this is -- first of all, this isn't
10 specific about TVT. This is as it applies to TVT.

11 So your question? I'm sorry, sir.

12 Q. Are there societies that have spoken out
13 against the use of mesh?

14 A. I think there are, yeah.

15 Q. Have you cited any of those in your report?

16 A. No.

17 Q. Why is that?

18 A. I'm citing -- I'm presenting my own opinions,
19 and this is -- this is -- I didn't think it was
20 appropriate. I didn't see any reason to.

21 Q. These are -- this is evidence that you're
22 citing that you believe supports your opinion; correct?

23 A. Right, correct.

24 Q. But there's no citation of the evidence that

1 doesn't support your opinion; right?

2 A. I'm not necessarily aware of what specific
3 societies have come out against the TVT, so, no, I'm not
4 aware of any in particular that have come out against
5 it, so there wouldn't be any reason to include that.

6 Q. I believe earlier, Doctor, when you were
7 talking about your reliance list, you said that there
8 may be some statements from societies that you had asked
9 counsel for when you were forming your opinions;
10 correct?

11 A. Yes, sir.

12 Q. Did you ask for all of the statements that
13 would have been contrary to mesh usage?

14 A. I specifically asked for some statements from
15 societies in particular that I rely on.

16 Q. Is the SGS a society that you rely upon?

17 A. I've been to a meeting and I did a
18 presentation, but I wasn't seeking their opinion about
19 this.

20 Q. Why is that?

21 A. I didn't know that they had an opinion on this.

22 Q. Is that because you didn't look?

23 A. I just didn't have -- I didn't know they had an
24 opinion on it.

1 Q. It would allow you to counsel a patient that
2 they may have dyspareunia which may not resolve?

3 A. I think unless it were -- that they may have
4 dyspareunia that may not resolve unless they had some
5 further treatment.

6 Q. And where in here does it say that some further
7 treatment may be necessary to relieve symptoms?

8 A. It's inherent in this. I mean, they don't --
9 they're not necessarily spelling out every single thing
10 on here, but it's inherent in these adverse reactions
11 what this can lead to.

12 Q. What was the reasoning behind putting specifics
13 in the 2015 IFU?

14 A. I'm not a part of that discussion.

15 Q. But it's your testimony here today that all of
16 these adverse reactions that are located within 14
17 bullet points are the same things that are warned about
18 and contained within the adverse reactions in Exhibit 18
19 within these four bullet points?

20 A. If you look here, let's look at No. 2 in the
21 old, transitory local irritation of the wound, if you
22 look at that, three of these bullet points say exactly
23 the one bullet point.

24 You can look at No. 2 on Exhibit 18 and then

1 make the statement, "Larger pore size also enhances
2 other favorable host responses, such as greater Type III
3 collagen deposition, greater capillary penetration, and
4 greater attachment strength."

5 Do you see that?

6 A. I do.

7 Q. You would agree that larger pore size is
8 better; correct?

9 A. In the context of mesh repairs, pore sizes
10 greater than 75 microns is essential.

11 Q. And, for you, the magic number is 75 microns?

12 A. Well, the magic number is not -- it's not my
13 magic number, sir.

14 Q. Whose is it?

15 A. It was postulated by a fella named Amid, and
16 there's reasons for that number.

17 Q. But fair to say that your opinion is that mesh
18 needs to be 75 microns in order to have a large enough
19 pore size?

20 A. By definition, macroporous measures greater
21 than 75 microns.

22 Q. Going to page 10, at the bottom there's a
23 statement that you make that says, "Although as yet
24 unpublished, our outcomes today have been favorable.

1 The overwhelming majority of such patients have
2 expressed extreme satisfaction with their experience,
3 and not infrequently the results have been
4 enthusiastically described as life-changing."

5 Do you see that?

6 A. I do.

7 Q. Why is your data unpublished?

8 A. Because it's unpublished. But it's unpublished
9 because of time constraints and because, as a solo
10 practitioner managing my own practice, doing my own
11 cases, doing all the work of a practice, that amount of
12 work, just it seems fairly daunting, but there's some
13 medical students who are working with me that might be
14 interested in helping do some of the legwork and get
15 some of that done. But it really is more of a time
16 issue than anything else.

17 The other thing about my data is it's not a
18 prospective type of data, so although it's, I think,
19 interesting and it's very useful for my own patients,
20 I'm not sure, in the big body of medical literature,
21 where it would fall out in that pyramid of hierarchy of
22 literature. So I think it's essential that the world
23 knows, other than I think it is interesting and would be
24 useful.

1 Q. You've never done lab research on
2 polypropylene; correct?

3 A. What do you mean by that, sir?

4 Q. Have you ever done research within a lab on
5 polypropylene?

6 A. I thought you said lab search. You said lab
7 research?

8 Q. Lab research.

9 A. Sorry about that. No.

10 Q. You've never done any type of pathological
11 analysis on explanted polypropylene mesh, have you?

12 A. I've not physically done that myself, no.

13 Q. You're not a biomaterials specialist; correct?

14 A. Again, I'm not paid to do anything like that.

15 Q. You've never published opinions that
16 polypropylene does not degrade in the human body, have
17 you?

18 A. I've never published that, no.

19 Q. You've never published opinions that
20 polypropylene does not create a foreign body reaction;
21 correct?

22 A. I've never published on that, so, no.

23 Q. You're not an expert on warnings; correct?

24 A. In terms of calling me an expert, in the

1 context of how I use these products and how I warn
2 patients, I think I am actually an expert in giving
3 warnings to patients. So if that's what you mean, yes,
4 but it may not be what you mean.

5 Q. What risk information are medical device
6 companies required to put in the IFU?

7 A. These are -- those are requirements that are
8 between them and the regulatory agencies.

9 Q. And you wouldn't be an expert on those
10 requirements; correct?

11 A. No.

12 Q. You're not a biomechanical engineer; correct?

13 A. No, I'm not paid to be a biomechanical
14 engineer.

15 Q. You're not an expert on the design of medical
16 devices, are you?

17 A. I use the devices a lot and I have opinions
18 about devices, but I'm not paid to design medical
19 devices.

20 Q. You've never designed a medical device
21 yourself; correct?

22 A. We've done a lot -- we've done some interesting
23 things. I don't know if I've designed. I've never
24 designed something to go to market, no.

1 We do what we have to do to get our job done,
2 and sometimes that requires improvisation, so I do some
3 designing, but I wouldn't call it -- I've never done
4 anything commercial, no.

5 Q. Who's "we"?

6 A. Me. Me and the nurses, actually. Sometimes
7 they help.

8 Or let me rephrase that. They always help.

9 Q. Do you know what standards a manufacturer must
10 follow in designing mesh products?

11 A. I think it's between them and the -- whoever
12 the regulatory agencies are, so, no.

13 Q. You wouldn't have any expertise in that;
14 correct?

15 A. Not in the manufacturing, no.

16 Q. Have you ever reviewed any of Ethicon's
17 internal standard operating procedures?

18 A. No.

19 Q. Have you ever authored a peer-reviewed article
20 on stress urinary incontinence?

21 A. No.

22 Q. Have you ever authored a peer-reviewed article
23 on midurethral slings?

24 A. No.

1 Q. Have you ever authored a peer-reviewed article
2 on any pelvic floor surgery?

3 A. I don't know if that bladder perforation thing
4 would be considered pelvic floor surgery, but absent
5 that, no.

6 Q. Do you consider yourself to be an expert on the
7 design of transvaginal mesh?

8 A. More on the use, not the design.

9 Q. I think we established you've never designed a
10 medical device yourself that was taken to market;
11 correct?

12 A. That is correct.

13 Q. Do you own any patents for any medical devices?

14 A. No.

15 Q. Have you ever sought to publish any of the
16 opinions you're offering here today in this litigation
17 within a peer-reviewed journal?

18 A. I have not.

19 Q. Have you ever been involved in any clinical
20 trials comparing midurethral slings to any other pelvic
21 surgery?

22 A. No.

23 Q. Have you ever been involved in a randomized
24 controlled trial involving transvaginal mesh treatment